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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,484	11/28/2001	Yen Choo	8325-2004 G8-US1	2713

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/996,484	Applicant(s) CHOO ET AL.	
	Examiner Daniel M Sullivan	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 34.

Claim(s) withdrawn from consideration: 1-5, 7, 8, 10, 11, 13-18, 21-26, 31, ~~34~~, 35 and 38-47.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendment to claim 34 introduces new limitations requiring that both the first and second polypeptides of the switching system bind to DNA and that the ligand binds to both polypeptides. As the previously examined claims did not recite these limitations, an additional search is required to determine patentability of the amended claims. Adequacy of the disclosure with regard to enablement and written description must also be reconsidered in view of the new limitations. In that regard, it is noted that page 53, line 18 of the specification, cited by applicant in support of the limitation that ligand bind to both polypeptide components of the complex, does not appear to disclose the invention as claimed. The passage cited reads, in full, as follows: "With regard to protein switches, the methods of the present invention typically involve using a tripartite configuration of one or more first polypeptide molecules, one or more ligands and one or more second polypeptide [sic] as described above to screen for (i) polypeptide binding molecules that bind to (another) target polypeptide in a manner that is modulatable by a ligand and/or (ii) ligands that modulate binding of two polypeptides to each other." Nothing in this teaching would suggest that the protein switch be limited to those in which ligand binds to both polypeptide components. Therefore, the limitation appears to add new matter..

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments with regard to patentability of the claims over the art of record are predicated on entry of the amendment and, as the amendment has not been entered, are moot. Applicant also comments that the Office does not make clear which of the proteins disclosed in Table 1 of McEwan binds DNA. On the contrary, the Final Office action states, "McEwan et al. describes in detail the DNA binding domain comprised within the glucocorticoid, estrogen and retinoid receptor proteins comprised within the switching systems disclosed in Table 1" (page 3). Thus, the Office Action makes clear that at least the glucocorticoid, estrogen and retinoid receptor proteins of the complex bind DNA. This is further illustrated for the glucocorticoid receptor in Figure 4.